

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Rafael Andino, Christopher Brooks, and  
Donald Van Royen

Application No. : Not yet assigned

Filed : July 15, 2003

For : APPARATUS AND METHODS FOR FACILITATING  
WOUND HEALING

Group Art Unit : Not yet assigned

Examiner : Not yet assigned

Hon. Commissioner for Patents  
Post Office Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. §§ 1.56 and 1.97,  
applicants wish to call the attention of the Examiner to the  
following documents:

U.S. Patents

Caesar	2,099,511	(11/16/37)
Horn	3,918,459	(11/11/75)
Ellis et al.	3,964,477	(06/22/76)
Ellis	4,019,510	(04/26/77)
Konikoff	4,142,521	(03/06/79)
Fairbanks	4,233,965	(11/18/80)
Donadelli	4,312,340	(01/26/82)
Greatbatch	4,313,438	(02/02/82)
Greatbatch	4,314,554	(02/09/82)
Wilson	4,398,545	(08/16/83)
Bryan	4,509,535	(04/09/85)
Brighton et al.	4,535,775	(08/20/85)
Maurer	4,556,051	(12/03/85)
Ibbott	4,619,252	(10/28/86)

#### U.S. Patents (cont'd)

Fuxue et al.	4,846,178	(07/11/89)
Miller	4,846,181	(07/11/89)
Takeuchi et al.	4,895,153	(01/23/90)
Bartelt et al.	4,895,154	(01/23/90)
Jones	4,911,688	(03/27/90)
Takeuchi et al.	4,922,906	(05/08/90)
Claude	4,982,742	(01/08/91)
Keusch et al.	4,989,607	(02/05/91)
Rogozinski	5,395,398	(03/07/95)
D'Alerta	5,423,874	(06/13/95)
Zanakis et al.	5,433,735	(07/18/95)
Scherson et al.	5,578,022	(11/26/96)
Becker et al.	5,814,094	(09/29/98)
Rise	5,853,424	(12/29/98)
Shoemaker, II	5,974,344	(10/26/99)
Kozhemiakin et al.	6,122,550	(09/19/00)
Millot et al.	6,411,853	(06/25/02)

#### Foreign Patents

PCT	WO 00/65993	11/09/00
EPO	EP 0 947 214 A3	10/06/99
PCT	WO 98/26838	06/25/98

#### Other Documents

Assimacopoulos, Dennis, "Low Intensity Negative Electric Current in the Treatment of Ulcers of the Leg Due to Chronic Venous Insufficiency," *American Journal of Surgery*: 115, 683-687 (1968).

Baker, Lucinda L., et al., "Effects of Electrical Stimulation on Wound Healing in Patients with Diabetic Ulcers," *Diabetes Care*: 20(3), 405-412 (1997).

Biedebach, Mark C., "Accelerated Healing of Skin Ulcers by Electrical Stimulation and the Intracellular Physiological Mechanisms Involved," *Acupuncture and Electro-therapeutics Research*: 14(1), 43-60 (1989).

Carley, Patrick J., et al., "Electrotherapy for Acceleration of Wound Healing: Low Intensity Direct Current," *Arch. Phys. Med. Rehab.*: 66, 443-446 (1985).

Davis, Stephen C., et al., "Electrical Stimulation and Ultrasound in Wound Healing," *Dermatologic Clinics*: 11(4), 775-781 (1993).

Dayton, Paul D., et al., "Electrical Stimulation of Cutaneous Ulcerations A Literature Review," *Journal of the American Podiatric Medical Association*: 79(7), 318-321 (Jul. 1989).

Feedar, Jeffrey A., et al. "Chronic Dermal Ulcer Healing Enhanced with Monophasic Pulsed Electrical Stimulation," *Physical Therapy*: 71(9), 639-649 (1991).

Fleischli, John G., et al. "Electrical Stimulation in Wound Healing," *The Journal of Foot & Ankle Surgery*: 36(6), 457-461 (1997).

Gault, Walter R., et al. "Use of Low Intensity Direct Current in Management of Ischemic Skin Ulcers," *Physical Therapy*: 56(3), 265-269 (March 1976).

Gentzkow, Gary D., et al., "Electrical Stimulation for Dermal Wound Healing," *Clinics in Podiatric Medicine and Surgery*: 8(4), 827-841 (1991).

Gentzkow, Gary D., "Electrical Stimulation to Heal Dermal Wounds," *Journal of Dermatologic Surgery and Oncology*: 19(8), 753-758 (Aug. 1993).

Gilcreast, Darlene M., et al., "Effect of Electrical Stimulation on Foot Skin Perfusion in Persons with or at Risk for Diabetic Foot Ulcers," *Wound Repair and Regeneration*: 6(5), 434-441 (1998).

Gogia, Prem P., "Physical Therapy Modalities for Wound Management," *Ostomy/Wound Management*: 42(1), 46-54 (1996).

Itoh, Masayoshi, et al., "Accelerated Wound Healing of Pressure Ulcers by Pulsed High Peak Power Electromagnetic Energy (Diapulse)," *Decubitus*: 4(1), 24-34 (1991).

Kloth, Luther C., "Physical Modalities in Wound Management: UVC, Therapeutic Heating and Electrical Stimulation," *Ostomy/Wound Management*: 41(5), 18-27 (1995).

Kloth, Luther C., et al., "Promotion of Wound Healing with Electrical Stimulation," *Advances in Wound Care*: 9(5), 42-45 (Sept./Oct. 1996).

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Lee, Raphael C., et al., "A Review of the Biophysical for the Clinical Application of Electric Fields in Soft-Tissue Repair," *Journal of Burn Care and Rehabilitation*: 14(3), 319-335 (May/June 1993).

Lundeberg, Thomas C.M., et al., "Electrical Nerve Stimulation Improves Healing of Diabetic Ulcers," *Annals of Plastic Surgery*: 29(4), 328-331 (1992).

Nicolle, Frederick V., et al., "Use of Radio-Frequency Pulsed Energy in the Control of Postoperative Reaction in Blepharoplasty," *Aesthetic Plastic Surgery*: 6, 169-171 (1982).

Rowley, Blair A., et al., "The Use of Low Level Electrical Current for Enhancement of Tissue Healing," *Biomedical Sciences Instrumentation*: 1, 111-114 (1974).

Šemrov, Deján, et al., "DC Electrical Stimulation for Chronic Wound Healing Enhancement. Part 2. Parameter Determination by Numerical Modelling," *Bioelectrochemistry and Bioenergetics*: 43:271-277 (1997).

Stefanovska, A., et al., "Treatment of Chronic Wounds by means of Electric and Electromagnetic Fields - Part 2: Value of FES Parameters for Pressure Sore Treatment," *Medical & Biological Engineering & Computing*: 31(3), 213-220 (May 1993).

Vodovnik, L., et al., "Treatment of Chronic Wounds by Means of Electric and Electromagnetic Fields - Part 1: Literature Review," *Medical & Biological Engineering & Computing*: 30(3), 257-266 (May 1992).

Weiss, Darryl S., et al., "Electrical Stimulation and Wound Healing," *Arch Dermatology*: 126, 222-225 (Feb. 1990).

Wheeler, Paul C., et al., "Neural Considerations in the Healing of Ulcerated Tissue by Clinical Electrotherapeutic Application of Weak Direct Current: Findings and Theory," *Neuroelectric Research*: 9, 83-99 (1971).

Wolcott, Lester E., "Accelerated Healing of Skin Ulcers by Electrotherapy: Preliminary Clinical Results," *Southern Medical Journal*: 62, 795-801 (July 1969).

Yarkony, Gary M., "Pressure Ulcers: A Review," *Archives of Physical Medicine and Rehabilitation*: 75(8), 908-917 (1994).

These documents are listed on the accompanying Form  
PTO-1449 (submitted in duplicate) and copies are enclosed  
herewith.

Consideration of the foregoing in relation to this  
patent application is respectfully requested.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "James A. Leiz", is written over a horizontal line.

James A. Leiz  
Reg. No. 46,109  
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FORM PTO-1449  U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE  INFORMATION DISCLOSURE STATEMENT BY APPLICANTS	ATTY. DOCKET NO. BIO-001 DIV.	APPLICATION NO. To be assigned
	APPLICANTS Rafael Andino et al.	
	FILING DATE July 15, 2003	GROUP

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	2,099,511	11/16/37	Caesar	188	408	
	3,918,459	11/11/75	Horn	128	419R	
	3,964,477	06/22/76	Ellis et al.	128	172.1	
	4,019,510	04/26/77	Ellis	128	172.1	
	4,142,521	03/06/79	Konikoff	128	82.1	
	4,233,965	11/18/80	Fairbanks	128	1.5	
	4,312,340	01/26/82	Donadelli	128	207.21	
	4,313,438	02/02/82	Greatbatch	128	207.21	
	4,314,554	02/09/82	Greatbatch	128	207.21	
	4,398,545	08/16/83	Wilson	128	798	
	4,509,535	04/09/85	Bryan	128	798	
	4,535,775	08/20/85	Brighton et al.	128	419	
	4,556,051	12/03/85	Maurer	128	1.5	
	4,619,252	10/28/86	Ibbott	128	82.1	
	4,846,178	07/11/89	Fuxue et al.	128	419F	
	4,846,181	07/11/89	Miller	128	421	
	4,895,153	01/23/90	Takeuchi et al.	128	421	
	4,895,154	01/23/90	Bartelt et al.	128	421	
	4,911,688	03/27/90	Jones	604	20	
	4,922,906	05/08/90	Takeuchi et al.	128	419R	
	4,982,742	01/08/91	Claude	128	798	
	4,989,607	02/05/91	Keusch et al.	128	640	
	5,395,398	03/07/95	Rogozinski	607	50	
	5,423,874	06/13/95	D'Alerta	607	72	
	5,433,735	07/18/95	Zanakis et al.	607	50	
	5,578,022	11/26/96	Scherson et al.	604	304	
	5,814,094	09/29/98	Becker et al.	607	50	
	5,853,424	12/29/98	Rise	607	117	

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	5,974,344	10/26/99	Shoemaker, II	607	149	
	6,122,550	09/19/00	Kozhemiakin et al.	607	101	
	6,411,853	06/25/02	Millot et al.	607	50	

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	WO 00/65993	11/09/00	PCT				
	EP 0 947 214 A2	10/06/99	EPO				
	WO 98/26838	06/25/98	PCT				

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